REMARKS

Claims 1 and 17-20 are pending and under examination in the subject application. No claim has been added, canceled, or amended herein. Accordingly, claims 1 and 17-20 are still pending and under examination.

In view of the remarks below, applicants maintain that the Examiner's rejections have been overcome, and respectfully request that they be withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1 and 17-20 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response, applicants respectfully traverse the Examiner's rejection.

The test for enablement is whether one skilled in the art could, at the time of the invention, make and use the claimed invention based on the disclosure and the information known in the art without undue experimentation. Applicants maintain that the claimed invention satisfies the test for enablement, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

The subject invention provides modified adenoviruses comprising mutant adenoviral genomic DNA. This invention is based on applicants' discovery that the E4 ORF6 protein expressed *alone* is sufficient to inhibit repair of double strand breaks or end-joining. Accordingly, the invention may be practiced using these adenoviral vectors to inhibit end-joining of DNA breaks.

In support of the rejection of claims 1 and 17-20, the Examiner alleges that the specification does not reasonably enable the claimed vectors because the specification does not teach how to make a virus in which no other early or late gene products are expressed except E4-ORF6. Accordingly, the Examiner concludes that one skilled in the art would not be able to use the invention commensurate with the scope of the claims.

Applicants disagree with the Examiner's position. First, applicants maintain that the specification as filed fully supports the claimed modified adenoviruses. Such support may be found in the specification, *inter alia*, at page 37, line 6 to page 38, line 26; page 49, line 24 to page 53, line 16; page 55, line 11 to page 56, line 1; and Figure 9. Accordingly, applicants maintain that the above teachings in the specification clearly enable one skilled in the art to practice the claimed invention.

Furthermore, applicants maintain that one skilled in the art would recognize the basic characteristic of the claimed modified adenoviruses. The techniques for constructing mutant vectors are well known in the art. Examples of assembling

such adenoviral vectors with mutant genomes are given through the Experimental Details section of the instant specification. These modified adenoviruses are constructed from mutant adenoviral genomic DNA which have disruptions in the E1 or E3 regions wherein the E4 region has been deleted and the E4 ORF6 is inserted into the mutant genome. Such manipulations described in the instant specification are also well-known to one skilled in the art. Accordingly, applicants maintain that the specification coupled with the information known in the art clearly enables one skilled in the art to practice the claimed invention.

The Examiner further rejected claims 1 and 17-19 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response, applicants respectfully traverse the Examiner's rejection.

The test for written description under 35 U.S.C. §112, first paragraph, is whether the disclosure describes the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. According to M.P.E.P. §2163(I)(A), "[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). The initial burden is therefore on

the Examiner to present evidence of the lack of written description. Furthermore, according to M.P.E.P. §2163(II)(A)(3)(a), "[a]n adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. Applicants maintain that the claimed invention satisfies the test for adequate written description, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

In support of the rejection, the Examiner alleges that only a modified adenovirus that does not express any gene products from E4 except ORF6 is adequately described. As the Examiner concedes, the specification discloses, *inter alia* at page 37, lines 19-21, that "[a]n adenoviral vector was constructed which expresses early region 4 ORF6 protein, in the absence of expression of any other adenovirus gene." Applicants therefore understand the basis of the rejection to be the Examiner's assertion that only the modified adenovirus of claim 20 is adequately described, that is, a modified adenovirus which only expresses E4 ORF6 and no other early or late genes.

Applicants disagree with the Examiner's position. The disclosure sets forth modified adenoviruses which express E4 ORF6 (as the sole E4 protein) either alone or with E1A and/or E1B. Support for modified adenoviruses which express either or both E1 regions in addition to the E4 ORF6 protein may be found in the specification, *inter alia*, at page 18, lines 12-31, which states that "viruses expressing E4 ORF6 and E1A

and/or E1B are constructed using existing viral mutant DNA genomes." Additional support may be found *inter alia* at line 26; page 49, line 24 to page 53, line 16; page 55, line 11 to page 56, line 1; and Figure 9. Applicants maintain that the disclosure of these various modified adenoviruses of the claimed invention is sufficient for a person skilled in the art to recognize that applicants were in possession of the claimed methods.

Moreover, according to M.P.E.P. §2163 (II)(A)(3)(a)(ii), the written description for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics sufficient to show the applicant was in possession of the claimed genus. *Regents of the University of California v Eli Lilly*, 119 F3d. 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). Satisfactory disclosure depends on whether the necessary common attributes of the genus are recognized by one skilled in the art in view of the species disclosed. It does not require that the description be so specific as to fully describe all species in the genus. Applicants maintain that the claimed genus is supported by the disclosed species, and that the species disclose the necessary attributes of the claimed genus.

The claimed genus comprises modified adenoviruses which only express the E4 ORF6, and/or E1A and/or E1B gene products. The disclosed species include modified adenoviruses which comprise E1A and E4 ORF6, E1B and E4 ORF6, E1A, E1B and E4 ORF6, and E4 ORF6 only. The expression of E4 ORF6 is one of the common attributes of the claimed genus. In light of the specification, one skilled in the pertinent art would

recognize this attribute as a potential therapeutic tool. Accordingly, applicants maintain that one skilled in the art would easily recognize the commonality of the claimed genus in view of the disclosed species.

In view of these remarks, applicants maintain that claims 1 and 17-19 are adequately supported by the disclosure and satisfy the requirements of 35 U.S.C. §112, first paragraph.

In view of these remarks, applicants maintain that claims 1, 17-20 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Conclusion

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

8/5/07

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